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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,432	10/03/2003	Herbert Andre Jansen	05015228-92US PTN/df	9015

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EXAMINER	
WOLF, MEGAN YARNALL	
ART UNIT	**PAPER NUMBER**
3738	
MAIL DATE	**DELIVERY MODE**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/677,432	**Applicant(s)** JANSEN ET AL.	
	Examiner Megan Wolf	**Art Unit** 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2011*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.
  4a) Of the above claim(s) *11-28* is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-10* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
  Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/3/11 has been entered.

Response to Arguments

2. Applicant's arguments filed 3/3/11 have been fully considered but they are not persuasive. Applicant argues that Sati does not disclose using the geometry of tools to calculate alterations as they are made on a bone. Upon a thorough reading of Sati it appears that Sati does disclose this feature. For instance, par.52 states, "The instruments 16 to be used on the patient 12 while performing the procedure are virtually represented on the images 24, and so are the implants. The 3D implant and instrument geometric models in combination are used with the registered medical images 24, and the generating 2D projections of that instrument and/or implant are updated dynamically in real-time as the implant/instrument is moved about in 3D space." Par.79 then specifically discloses "As the femur is being rasped, the length is continuously calculated along the anatomical axis of the femur, V_{femur}, relative to the femoral tracker, T_f *by monitoring the position of the reamer*."

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2, 3, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "said information about the current implant insertion" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitation "guiding an operator in altering the femur" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-5 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Sati et al. 2005/0203384 (hereafter referred to as Sati).

Re claim 1, Sati discloses a method of doing surgical treatment with a tracking system in computer-assisted surgery for guiding an operator in inserting a femoral implant of a hip joint implant in a femur as a function of a limb length and orientation of the femoral implant, comprising the steps of obtaining a frame of reference of the femur, the frame of reference being trackable in space (pars.37 and 50), obtaining a digital model of a femoral implant (pars.12, 27, and 38-40) and a digital model of a geometry of a tooling end of a rasp (pars.30, 33, 52, 63, and 64), calculating a desired implant insertion for the femoral implant with respect to the frame of reference of the femur, as a function of the limb length (pars.27, 39, 59, and 77), calculating alterations being made to a femur with real-time tracking of the rasp altering the femur for receiving the femoral implant and with the digital model of the geometry of the tooling end of the rasp (pars.33, 52, 63, 64, and 79) and determining a current implant insertion with respect to the desired implant insertion, the current implant insertion being calculated as a function of the digital model of the femoral implant and the alterations (pars.77-80).

Re claim 2, see pars. 64, 71, 72, and 80.

Re claim 3, see par. 77.

Re claim 4, see par. 84.

Re claim 5, see pars. 37 and 50.

Re claim 10, see pars. 33, 64, 72, and 84.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sati as applied to claim 5 above, and further in view of Carson 2002/0198451 (hereafter referred to as Carson).

Re claim 6, Sati discloses the invention substantially as claimed and as discussed above. Sati further discloses using the center of the femoral head as a frame of reference of the femur (par.93). However, Sati does not disclose the specific steps of determining the center of the femoral head including positioning a reference system trackable in space for position and orientation onto the femur, dislocating the femur from the pelvis, creating a digital model of a surface of the femoral head as a function of the reference system, and calculating the center of the femoral head as a function of the digital model of the surface of the femoral head.

Carson teaches a CAS method, in the same field of endeavor, wherein a probe is used to designate a number of points on the femoral head for the purpose of allowing the computer to calculate the geometrical center which corresponds to the geometry of points collected (par.66).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the method taught by Carson of digitizing points on the femoral head in order to calculate the center of the femoral head in the method of Sati.

Re claim 8, while Sati in view of Carson does not specifically disclose using the acetabulum to calculate the center of the femoral head, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the same method of surface digitization taught by Carson but applied to the acetabulum since the acetabulum and femoral head share a center of rotation. Using the surface of the acetabulum as opposed to the surface of the femoral head is a matter of design choice because applicant's specification does not disclose that using the acetabulum solves any stated problem or is for any particular purpose. Moreover, it appears that the method would perform equally well using the acetabulum rather than femoral head.

9. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sati in view of Carson as applied to claims 6 and 8 above, and further in view of Chen et al. 2004/0087852 (hereafter referred to as Chen). Sati in view of Carson discloses the invention substantially as claimed and as discussed above, but does not specifically disclose establishing femoral sagittal, frontal, and transverse planes by registering a sagittal plane with respect to the reference system by digitizing the anatomical axis of the femur, a midpoint of the epicondyles and a midpoint of a tibia corresponding to the femur, the anatomical axis and the midpoint of the malleoli lying in the sagittal plane, registering a frontal plane with respect to the reference system, and registering a transverse plane with respect to the reference system.

Chen teaches a CAS method, in the same field of endeavor, wherein points on the anatomy are digitized and used to create frontal, sagittal, and transverse planes (pars.14, 64-67, 74, 76) for the purpose of defining a three-dimensional coordinate system available for use in a computer-assisted surgical system for ascertaining position and alignment of an object with respect to an anatomical structure (pars.17, 21-23).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the steps taught by Chen for establishing a coordinate system on an anatomic structure with the method of Sati in view of Carson in order to improve the accuracy of the positioning of the tools and instruments during the surgical procedure. Since Sati specifically discloses critical positions of the instruments and femoral implant with respect to the anatomic femur, including leg length, inclination (varus/valgus angle), and anteversion, it would have been obvious to specifically define the planes with respect to the anatomic femur using known bony landmarks in order to further aid in the correct positioning of the instruments and implant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738

/CORRINE M MCDERMOTT/
Supervisory Patent Examiner, Art Unit 3738